

August 10, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 2004N-0264

Farmers Cooperative Company of Farnhamville, IA submits these comments in response to the advance notice of proposed rulemaking published on July 14, 2004 by the Food and Drug Administration and U.S. Department of Agriculture seeking comments on federal measures to mitigate further the risk of bovine spongiform encephalopathy (BSE) in the United States.

Farmers Cooperative Company is one of the largest locally owned and operated agricultural supply cooperatives in the United States. Farmers Cooperative Company manufactures more than 350,000 tons of animal feed annually at six feed manufacturing plants and operates over 40 locations in northern and central Iowa handling more than 85,000,000 bushels of grain annually.

At the outset, Farmers Cooperative Company would like to commend the FDA for having previously utilized a science and risk based approach to regulatory policies designed to prevent the establishment or amplification of BSE in the United States. The science and risk based approach the U.S. has taken in regards to BSE is one of the principal reasons the FDA feed rule implemented in 1997 has enjoyed such an extraordinary level of compliance – exceeding 99 percent – the most successful compliance rate of any FDA regulation. We believe that FDA should view its future regulatory actions from the context of the U.S. and North American experience with the BSE issue, which is dramatically different from the sequence of events and policy responses that unfolded in Europe when this disease was discovered more than 15 years ago.

We also believe that as FDA proceeds to develop a proposed rule concerning the removal of so-called specified risk materials (SRMs) from all animal feed, it is critically important that the agency continue to base its decision-making on the best available science and prudent risk-assessment measures based on the facts known today. To deviate from that sound course could jeopardize the animal agriculture industry and in the long-term undermine consumer confidence in our food supply. We recognize that science is not static, and that the agency and the feed industry have a responsibility to base future decisions on the best available facts that exist.

Farmers Cooperative Company wishes to focus our comments on a limited number of the 30 separate issues or questions that FDA is seeking comments in response to the advanced notice of proposed rulemaking choosing to focus our comments to questions we have the most information and knowledge in regards to. The questions Farmers Cooperative Company would choose to comment on are as follows:

2004 N-0264

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- 1) Our comments on the proposed ban of all SRMs in all animal feeds, including scientific data and the economic and environmental impacts of prohibiting SRMs from use in all animal feed.
- 2) Our comments on requiring dedicated facilities, equipment, storage and transportation as a necessity to ensure that cross contamination is prevented and how an SRM ban of any sort would impact the feed industry as it applies to our company.
- 3) Our comments on FDA's question supporting a ban on all mammalian and avian meat and bone meal (MBM) in ruminant feed.
- 4) Our comments on FDA's question regarding possibly prohibiting bovine blood or blood products and plate waste from ruminant feed.

Farmers Cooperative Company's comments on the proposed ban of all SRMs in all animal feeds, including scientific data and the economic and environmental impacts of prohibiting SRMs from use in all animal feed.

Farmers Cooperative Company believes that some form of SRM removal, in particular a ban on brain and spinal cord of cattle 30 months or older, warrants consideration by FDA as the centerpiece of a proposed rule that would further reduce what already is an extremely low risk of BSE in the United States. We believe this policy is consistent with the approach recommended by Dr. William D. Hueston of the University of Minnesota's Center for Animal Health and Food Safety and the sole U.S. member of the BSE International Review Team. Dr. Hueston stated at the 108th annual National Grain & Feed Association convention in March 2004 that removal of brain and spinal cord from cattle 30 months or older was the single most important step that could be taken to prevent amplification of BSE in the United States.

It is our understanding that 90 percent of the total potential BSE infectivity exists in the brain and spinal cord if an animal is infected with BSE, and that virtually all of the potential infectivity remaining in other central nervous system tissues is eliminated through normal rendering processes. Since BSE has not been detected in an animal less than 30 months of age and that almost 85 percent of the cattle slaughtered in the U.S. each year are under 30 months of age, the SRM removal of brain and spinal cord from cattle 30 months or older would appear to be more prudent than a full SRM ban, as is being proposed. We believe that removing the vast majority of potential infectivity at the "top of the pyramid" for animal based feed ingredients would drastically reduce any potential for cross-contamination of feeds and feed ingredients at the rendering plant as well as at the feed manufacturing plant or through accidental mis-feeding.

The removal of brain and spinal cord from cattle 30 months or older from the animal food and feed chain would greatly reduce the need for FDA to implement additional regulatory controls that ultimately may be less protective of animal health, more disruptive, more costly and much more difficult or problematic to enforce. The removal of the brain and spinal cord materials, which potentially contain 90 percent of any possible infectivity, would drastically reduce down-stream regulatory controls needed towards banning of additional feed ingredient items from ruminants that are addressed later in these comments. Farmers Cooperative Company supports the position of the National Grain & Feed Association in which they are recommending that FDA contract with the Harvard Center for Risk Analysis to conduct an analysis using the mathematical model Harvard developed for USDA to quantify additional BSE risk reduction that would

result from a policy menu using the ban on brain and spinal cord from cattle 30 months or older combined with existing FDA BSE-Regulations and the excellent compliance rate those regulations have achieved.

We believe that prohibiting all SRMs from all animal feed would have a major economic and environmental impact. Rendering industry estimates that total wet waste disposal would be approximately 90 – 120 pounds per animal for removal of all SRMs from cattle 30 months of age or older. Waste disposal for full SRM removal in cattle 30 months or younger would amount to 30 – 60 pounds per animal. (The lower figure is based upon removal of the small intestine from the animal as opposed to the higher number representing removal of the entire intestinal tract). This would amount to generation of approximately 1.5 billion pounds of SRM material to dispose of annually.

By comparison, removal of brain and spinal cord material from cattle 30 months or older would involve an estimated wet waste removal of 2 pounds of SRMs per animal and an estimated 16 million pounds of waste material generated annually. This amounts to 1 percent of the waste material generated and required to be disposed of as compared to a full SRM removal from all cattle. The economic ramifications of disposal of 2 pounds of SRMs per animal versus 90 – 120 pounds per animal annually are staggering as they amount to millions as compared to billions of dollars.

Currently, animal feed and land-fill disposal are the only approved options for disposing of SRMs. It is believed that packing and rendering industries are exploring alternative industrial uses such as energy co-generation from these SRMs as well as other disposal options. In this regard we believe the U.S. government should consider providing economic incentives or remuneration to packers and renderers affected by such a policy change.

Farmers Cooperative Company's comments on requiring dedicated facilities, equipment, storage and transportation as a necessity to ensure that cross contamination is prevented and how an SRM ban of any sort would impact the feed industry as it applies to our company.

As documented by FDA's own BSE-compliance inspection data, most commercial feed manufacturers have made a voluntary business decision to dedicate a production facility, either because they believe it represented the easiest and most effective method to comply with the BSE-prevention rule or due to recommendations from insurance carriers or customers. Our company has dedicated our feed production plants to not utilizing prohibited mammalian protein products over the last few years. We believe that with the proposed ban on SRMs, either in total or a partial ban as we are suggesting, that feed systems in the U.S. will have a dramatically reduced risk of contamination from potential infective material with the removal of SRM material at the "top of the pyramid" which as mentioned previously are the materials most likely to be infected if a ruminant animal would in fact be found positive for BSE.

Farmers Cooperative Company does believe FDA should consider requiring that equipment used at rendering establishments that process animals from multiple species, including ruminants, and/or that process ruminant-derived SRMs be dedicated solely to handling mammalian material prohibited from being fed to cattle or other ruminants. We believe this is a sector of the industry at the "top of the pyramid" where the potential for cross-contamination and the potential impact on down-stream users is the greatest.

Farmers Cooperative Company also firmly believes that FDA should practice “trace-forward” inspection processes as much as possible by focusing government-based surveillance and enforcement on direct purchasers of mammalian material prohibited from being fed to ruminants to ensure that the product is being directed to and sold to firms that are using this material properly. In this regard, FDA should consider and implement means to access distribution records of rendering and animal protein blenders to accurately determine where product is being sold and used in feed manufacturing or in animal feeding operations.

Farmers Cooperative Company believes the economic impacts of requiring dedicated facilities, equipment, storage and transportation would be significant, particularly in the transportation sector. Requiring dedicated facilities, equipment, storage and transportation would result in establishments being required to discontinue the use of ruminant-derived feed ingredients during a period of escalating plant-based protein costs and reduced availability, such as what has occurred this past year with soybean meal market escalations. Firms would also be required to purchase additional transportation conveyances to transport ruminant-derived ingredients and feed products made from these ingredients. Impacts on the truck transportation sector would be severe and potentially very difficult to enforce. The cost of adding additional hopper-bottom trailers to haul dedicated feed ingredients is approximately \$40,000 per trailer while the cost of adding additional auger-unloading feed trailers is approximately \$60,000 per trailer. These costs would likely force many renderers and feed manufacturers to change their way of operating as they would no longer be competitive in the market place.

Farmers Cooperative Company’s comments on FDA’s question supporting a ban on all mammalian and avian meat and bone meal (MBM) in ruminant feed.

Farmers Cooperative Company believes there is no scientific justification for banning avian or other mammalian (porcine or equine) meat and bone meal from ruminant feed since these materials have never been shown to harbor BSE infectivity. Further, removing brain and spinal cord of cattle 30 months or older from the animal food/feed chain and retention of the current BSE-prevention feed rule’s clean-out requirements conceivably would effectively minimize the potential for cross-contamination. We believe a strategy of removal of brain and spinal cord from cattle 30 months or older combined with the redundancies of a systems-based approach to preventing BSE transmission would make a ban on mammalian and avian material in ruminant feed unnecessary. Further we believe it would be an unwarranted step based upon science and would greatly limit and increase the costs of protein sources remaining available to ruminant feed manufacturers and ruminant feeders.

Farmers Cooperative Company’s comments on FDA’s question regarding possibly prohibiting bovine blood or blood products and plate waste from ruminant feed.

Farmers Cooperative Company is not aware of any scientific evidence implicating bovine blood or blood products in either the natural or mechanical transmission of BSE. Based upon the Harvard Risk Assessment Model mentioned earlier in our comments, the conclusion that was arrived at by this assessment model was that the use of bovine blood as a feed ingredient for ruminants would not amplify BSE in the U.S. cattle population. Further, the recommendations of the International BSE Review Team did not raise blood and blood products as a material of concern. During a public meeting to present its findings in February of this year, the chair and U.S. member of the International Review Team specifically stated that blood and blood products were not a risk factor for BSE transmission. Thus our belief that the

rationale used by FDA in 1997 in the original BSE rule regarding the minimal risk of these materials as a transmitting agent of BSE and TSE's to ruminants remains valid.

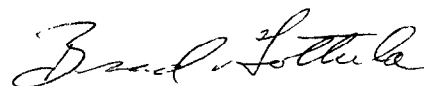
Plate waste has never been shown to pose a risk of infectivity to cattle or other ruminants, but rather has been considered primarily as a method to assist FDA in perfecting an analytical test to determine whether traces of prohibited material is or is not present in finished feed. Further, since implementation by USDA's Food Safety and Inspection Service in January of 2004 of its ban on all SRMs in human food, these potentially infective tissues no longer would be present in plate waste.

In short, the scientific basis for these exemptions has not changed. Banning these materials from use in ruminant feeds would have severe economic impacts for cattle feeders, particularly in the dairy industry.

Conclusion

Farmers Cooperative Company realizes that science is ever-changing and that we are still learning about BSE, which is a relatively new animal disease. At some point in the future it may be necessary to consider additional risk-mitigation steps either because of emerging science or data on the prevalence of BSE in the United States and other countries in North America. We strongly believe the proposal to ban brain and spinal cord SRMs from cattle 30 months or older would be a more prudent, less costly and equally effective method of strengthening BSE Regulations in the U.S. as they apply to feed ingredient suppliers, feed manufacturers and animal feeders. We urge the FDA to strongly consider this proposed measure instead of a more onerous plan of banning all SRMs from all cattle. We appreciate the opportunity to provide our input and views on this advance notice of proposed rulemaking and we pledge our continued efforts to achieve the objective of preventing the establishment or spread of BSE in the United States.

Sincerely,

A handwritten signature in black ink, appearing to read "Brad Gottula". The signature is fluid and cursive, with the first name "Brad" and last name "Gottula" clearly distinguishable.

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